REMARKS

This application has been carefully reviewed in light of the Office Action dated August 2, 2007. By way of this amendment, claims 3 and 5 have been amended and claims 7-21 have been cancelled. Claims 1-6 are currently pending in the application. Applicant hereby requests further examination and reconsideration in view of the following remarks.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-7 under 35 U.S.C. § 112, second paragraph, as being indefinite. This ground of rejection is respectfully traversed.

The Examiner states that the distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol in claim 1 is unclear. While not specifically stated in the office action, it appears that the basis for the Examiner's assertion that the distinction is unclear is that polyvinyl acetate and polyvinyl alcohol could be considered to be hydrophilic polymers. However, as stated in MPEP 2173.02, the "test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification,'" *quoting Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The present specification describes including both polyvinyl acetate and polyvinyl alcohol in the second paragraph on page 5, and mentions mixing polyvinyl acetate and polyvinyl alcohol to lower surface tension. In the next paragraph on page 5, the specification describes including a hydrophilic polymer to achieve a certain oncotic pressure. Thus, when claim 1 is read in light of the specification, one skilled in the art would recognize that the hydrophilic polymer recited in claim 1 is in addition to the polyvinyl acetate and polyvinyl alcohol.

Applicant respectfully submits that the language of claim 1 points out the subject matter with a reasonable degree of clarity and particularity.

The Examiner has also pointed out that the use of the trademark AMISOL in the claims is improper. Applicant has amended the claims such that the trademark is no longer recited in any claims.

Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Suzuki et al in combination with Guy et al and Holly. The Examiner has also rejected claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Suzuki et al in combination with Guy et al and Holly, and further in view of "applicant's statements of prior art." These grounds of rejection are respectfully traversed.

Independent claim 1 recites a composition for ophthalmic use comprising polyvinyl alcohol, polyvinyl acetate, a hydrophilic polymer, and a phospholipid.

Suzuki et al discloses an emulsion composition, the primary components of which are: 1) one drug selected from the group consisting of fluorometholone, clobetasone butyrate and clobetasol propionate, 2) a phospholipid, 3) liquid paraffin, and 4) water (see column 2, lines 5-14). In the last paragraph of column 6, Suzuki et al mentions other non-essential components that can be included in the emulsion. These additional components include thickeners such as polyvinyl pyrrolidone and polyvinyl alcohol, among others. Examples 16 and 23 describe using polyvinyl alcohol but not polyvinyl pyrrolidone. Examples 17 and 24 describe using polyvinyl pyrrolidone but not polyvinyl alcohol. Suzuki et al does not disclose using both polyvinyl pyrrolidone and polyvinyl alcohol in the same composition. Thus, Suzuki et al describes a composition including a phospholipid and a hydrophilic polymer (i.e., polyvinyl

pyrrolidone) and a composition including a phospholipid and polyvinyl alcohol, but does not disclose a composition that includes the three components of a phospholipid, polyvinyl pyrrolidone, and polyvinyl alcohol.

Guy et el discloses a therapeutic suspension comprising A) a drug, B) a suspending agent, C) a surface active agent, and optionally, D) tonicity agents and E) preservatives. Guy et al mentions in column 4 that compounds such as PVP and PVA, among others, can be used as the suspending agent or component (B). Guy et al does not teach using both PVP and PVA in the same compound.

Accordingly, the combination of Suzuki et al and Guy et al does not suggest a composition that includes the three claimed components of polyvinyl alcohol, a hydrophilic polymer, and a phospholipid. At best, this combination suggests a composition including a phospholipid and polyvinyl alcohol or a composition including a phospholipid and a hydrophilic polymer, but not all three components together.

The combination of Suzuki et al and Guy et al also fails to suggest a composition that includes the claimed component polyvinyl acetate. The Examiner asserts that it would have been obvious to add polyvinyl acetate to Suzuki et al because the combination of polyvinyl acetate and polyvinyl alcohol is synergistic as taught by Holly. Holly does disclose that by mixing polyvinyl acetate and polyvinyl alcohol it is possible to lower the surface tension of the solution while forming a completely wettable adsorbed layer over hydrophobic surfaces (see column 4, lines 25-29 of Holly). This is disclosed in Holly as being beneficial in increasing tear film stability; instability of the tear film being a problem the Holly patent is concerned with (see column 1). However, Suzuki et al is not concerned with tear film instability. Instead, as described in column 1 of Suzuki et al, this reference is concerned with increasing the solubility of drugs such as fluorometholone, clobetasone butyrate and clobetasol propionate so as

to facilitate dispensing these drugs via aqueous eye drops. There is no suggestion that lowering surface tension by adding polyvinyl acetate to the polyvinyl alcohol already present in the Suzuki et al composition will improve the ability to dispense drugs such as fluorometholone, clobetasone butyrate and clobetasol propionate. Accordingly, one of ordinary skill in the art would not have been taught by Holly to add polyvinyl acetate to the compositions of Suzuki et al and/or Guy et al.

Moreover, even if Suzuki et al and/or Guy et al were modified to include polyvinyl acetate as suggested by the Examiner, this modification would simply be adding polyvinyl acetate to a composition including a phospholipid and polyvinyl alcohol or a composition including a phospholipid and a hydrophilic polymer, not to a composition containing all three of a phospholipid, polyvinyl alcohol and a hydrophilic polymer. The combination of Suzuki et al, Guy et al and Holly thus fails to suggest providing a composition having all four of the components recited in claim 1.

For the above reasons, it is respectfully submitted that independent claim 1 is allowable over the combination of Suzuki et al, Guy et al and Holly. Claims 2-6 depend from claim 1 and are thus also believed to be allowable. Furthermore, at least some of these dependent claims set forth limitations not met by the prior art. For instance, claim 2 recites that the phospholipid is formulated in polysorbate-80, glycerin, ethanol, and water. The combination of Suzuki et al, Guy et al and Holly fails to suggest using a phospholipid formulated in polysorbate-80, glycerin, ethanol, and water. The Examiner contends that Suzuki et al discloses using solvents such as ethanol. Suzuki et al does describe using a solvent such as ethanol for preparing the emulsion, but as stated in lines 44-46 of column 7, the solvent is subsequently distilled off. Accordingly, the finished emulsion does not actually contain ethanol. Thus, the prior art references relied on by the Examiner do not suggest using a phospholipid

formulated in polysorbate-80, glycerin, ethanol, and water. With respect to the alleged "applicant's statements of prior art," the Examiner argues that applicant's specification states "that the combination of lecithin, ethanol, glycerol, polysorbate 80 is readily available in the market under the trade name Amisol." However, just because a product is commercially available does not mean that it would have been obvious to use that product in the claimed composition. Nothing in the prior art teaches using Amisol or a similar product as a source of a phospholipid in the claimed composition.

Claim 4 recites that the composition further includes one or more electrolytes to contribute to the well-being of the corneal epithelium. The prior art does not disclose any such electrolytes.

Claim 6 recites specific concentrations of polyvinyl alcohol, polyvinyl acetate, and polyvinyl pyrrolidone in the composition. However, there is no indication that the prior art teaches or suggests these claimed concentration levels.

Summary

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration of the objections and rejections is requested. Allowance of claims 1-6 at an early date is solicited.

Respectfully submitted,

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